Re-evaluation Decision RVD2014-03

Special Review Decision for Compound 1080

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Special Review Decision for Compound 1080

After a special review of the predacide Compound 1080 (sodium monofluoroacetate), Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is granting continued registration, as amended, of products containing Compound 1080 for sale and use in Canada.

An evaluation of available scientific information found that products containing Compound 1080 do not pose unacceptable risks to the environment provided new risk-reduction measures are included on the labels of all products as a condition of continued registration. No additional data are required.

The regulatory approach for the special review of Compound 1080 was first presented in Re-evaluation Note REV2013-04, *Special Review of Compound 1080,*[1] a consultation document.[2]

This special review decision[3] describes this stage of the PMRA's regulatory process for the special review of Compound 1080 as well as summarizes the Agency's decision and reasons for it.

Comments received during the consultation period were taken into consideration. Appendix I summarizes the comments received during the consultation period and provides the PMRA's response to these comments. Appendix II outlines the revised label statements.

To comply with this decision, registrants of end-use products containing Compound 1080 formulated as tablets will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

What is Compound 1080?

Compound 1080 is an animal toxicant used to control wolves and coyotes in the provinces of Alberta and Saskatchewan only. Products containing this active ingredient are registered as restricted-class products. Two formulations exist as either tablets or livestock collars with liquid containing Compound 1080. Compound 1080 can be applied as meat baits containing tablets or as a collar device on livestock. Application ranges from 1–12 tablets (5 mg/tablet of Compound 1080) in meat baits relative to the size of the bait (larger baits require more tablets) or one 60 mL collar device (10 mg/mL of Compound 1080) per livestock.

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1 *Special Review of Compound 1080*, REV2013-04, 29 August 2013.

2 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

3 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Environmental Considerations

What Happens When Compound 1080 is Introduced Into the Environment?

Compound 1080 poses a risk to birds and mammals; therefore, additional risk-reduction measures need to be observed.

Compound 1080 can enter the environment when meat baits containing the tablet formulation of this chemical are deployed to attract and kill nuisance wolves and coyotes. Use of this product is severely restricted as it is highly toxic to birds and mammals. Mammals are the most sensitive species particularly canids (for example, dogs). Non-target carnivores may also be exposed to Compound 1080 if they are attracted to bait stations and ingest any tablets. In order to further mitigate risk to non-target birds and mammals, additional label restrictions are required on product labels relating to how the product may be used. In recognition of species at risk which are known to exist in areas where Compound 1080 may be applied, an additional label restriction to prohibit use of Compound 1080 in these designated areas is also required.

Compound 1080 is highly water soluble and not bioaccumulative, hence it is not expected to be persistent and does not meet any of the Track 1 criteria under the Toxic Substances Management Policy.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The following additional key risk-reduction measures are required to address potential environmental risks identified in the special review. These measures, in addition to those already present on existing Compound 1080 product labels, are intended to minimize risks to the environment.

Additional Key Risk-Reduction Measures

Environment

- To minimize risk to non-target species, additional statements are required on product labels to further reduce the potential for exposure. These statements include use directions relating to:
    - Burying of multi-dose baits for the control of coyotes;
    - Placement of tablets deep into cuts made in carcasses to reduce exposure to scavenging birds;
    - Destruction and disposal of poisoned carcasses;
    - Disposal of vials or unused compound 1080 product; and
    - Addition of a statement prohibiting use of Compound 1080 in designated areas where species at risk exist.

What Additional Information is Being Requested?

The risk to the environment has been found to be acceptable when all risk-reduction measures are followed and implemented. No additional information is being requested from registrants as a result of this special review.

Other Information

Any person may file a notice of objection[4] regarding this decision on Compound 1080 within 60 days from the date of publication of this Special Review Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website, Request a Reconsideration of Decision, or contact the PMRA's Pest Management Information Service.

4 As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

The PMRA received comments in response to Re-evaluation Note REV2013-04, *Special Review of Compound 1080*, from stakeholders including registrants and the public. The PMRA has consolidated and summarized the comments received and provides responses below.

1.0 Comments relating to the burying of multi-dose baits to target coyotes

Stakeholders commented that the burying of a large bait to reduce the risk to non-target birds destroys the effectiveness of baiting a coyote-killed carcass at the predation site. It is acknowledged that burying the baits may protect non-targets like birds from accessing the bait, but buried bait will also be less attractive to a targeted coyote that is actively preying on livestock. The goal is to reduce and prevent active livestock predation. Imposing this restriction would remove the usefulness of multi-dose baits as a tool for controlling these incidences of predation.

PMRA Response

Taking into consideration this comment as well as consulting provincial government representatives from Alberta and of Saskatchewan, the PMRA acknowledges that if a coyote killed carcass is tampered with (moved, buried, etc.), the specific individual animal responsible for the kill would not consume the carcass. Therefore, burying the multi-dose baits would be ineffective in targeting the specific coyote responsible for the kill. In this scenario, the PMRA agrees that the specific coyote-killed carcass should not be buried, but will only be allowed to contain a maximum of three tablets instead of six. If a specific individual coyote is not being targeted, the requirement for burying multi-dose baits still stands. The required label amendments have been revised to reflect this consideration.

The PMRA also acknowledges that wolves are not as sensitive to the tampering of carcasses and as such the burying of multi-dose baits is still required.

2.0 Comments relating to species at risk statement

Stakeholders commented that the statement was too vague and may be interpreted to imply that the product cannot be used at all within the province where species at risk may be present. It was suggested that the statement be revised to clarify that it is a specific area within the province for which products cannot be used.

PMRA Response

The PMRA agrees with the suggestion and the required label amendments have been revised to reflect this consideration.

Appendix II Label Amendments for Products Containing Compound 1080

The following label amendments are required for registered end-use products formulated as tablets.

Registration Number 18300 – Alberta

In the section called **RESTRICTED USES, COYOTE**, under the **Multi Dose Bait** heading, the following sentence must be removed:

> *Place up to six tablets into a carcass at a coyote control site.*

Replace with:

> *Place up to six tablets into a carcass at a coyote control site and then cover with 30 cm of snow or 15 cm of loose soil.*
>
> *For targeting specific individual coyotes, place up to three tablets into a coyote killed carcass at the predation site.*

Under the **Use Limitations** section, the following statements must be added:

> *Tablets inserted into a carcass should be placed deep in a horizontal cut to prevent scavenging birds from accessing the tablet.*
>
> *For use only to control offending animals in areas where proper herd management is practiced to discourage predation.*
>
> *To prevent hazard of secondary poisoning, any baits removed from use or the carcasses of poisoned coyotes or wolves must be burned or buried to a depth of 60 cm (2 feet). Vials and unused product must be disposed of in accordance with provincial requirements.*
>
> *Do not apply this product if species at risk (for example the swift fox) that may feed on Compound 1080 bait or on poisoned carcasses are present in your (local or specific) area. For information on species at risk in your area, contact the Fish and Wildlife Division of Alberta Sustainable Resource Development.*

The following limitation should be **removed**:

> *The user of tablets must remove and destroy poison bait within 30 days of placement between April and October 31st and within 90 days of placement between November and March 31st.*

Registration Number 25857 – Saskatchewan

In the section called **RESTRICTED USES, COYOTE**, under the **Multi Dose Bait** heading, the following sentence must be removed:

Place up to six tablets into a carcass at a coyote control site.

Replace with:

Place up to six tablets into a carcass at a coyote control site and then cover with 30 cm of snow or 15 cm of loose soil.

For targeting specific individual coyotes, place up to three tablets into a coyote killed carcass at the predation site.

Under the **Limitations** section, the following statements must be added:

Tablets inserted into a carcass should be placed deep in a horizontal cut to prevent scavenging birds from accessing the tablet.

Do not apply this product if species at risk that may feed on Compound 1080 bait or on poisoned carcasses are present in your area. For information on species at risk in your area, contact the Saskatchewan Ministry of Environment Fish and Wildlife Branch.

The following limitation must be revised:

To prevent hazard of secondary poisoning, any baits ***removed from use*** *or the carcasses of poisoned coyotes or wolves must be burned or buried to a depth of 60 cm (2 feet). Vials and unused product must be disposed of in accordance with provincial requirements.*